Statement of
Rep. Henry A. Waxman, Ranking Minority Member
Committee on Government Reform
Hearing on
The Nation's Flu Shot Shortage: Where Are We Today and How Prepared Are We for Tomorrow?

November 17, 2004

Thank you, Chairman Davis, for holding this hearing on the flu vaccine shortage. You and I share the goal of establishing a healthy vaccine supply in the United States, and effective government oversight is an important part of this process.

This year's flu vaccine crisis raises three important oversight questions.

The first question is how the United States came to depend on just two companies for flu vaccines. The Institute of Medicine, the Government Accountability Office, and the National Vaccine Advisory Committee have all issued reports exposing the weakness of our national vaccine infrastructure. We cannot afford to continue to ignore their recommendations.

The second question is why the vaccine shortage led to such confusion and chaos. In a series of reports over the last four years, GAO repeatedly warned that the United States does not have a plan to ensure that the highest-risk people are immunized in the event of a shortage. The seniors who have been standing in lines for hours trying to get a flu vaccine know that GAO was right.

The third question is the primary subject of today's hearing: Did FDA do its job to protect the U.S. vaccine supply?

Since the vaccine shortage began, senior Administration officials including Acting FDA Commissioner Lester Crawford have been reassuring the public that FDA made no mistakes and did everything possible to protect the vaccine supply.

Today, we will evaluate these claims.

On October 13, Chairman Davis and I asked FDA to provide copies of documents relating to its oversight of the Chiron vaccine plant in Liverpool, England. This is the plant that British regulators shut down on October 5, causing the United States to lose approximately half of its supply of flu vaccine.

We have now received and reviewed over 1,000 pages of documents. We've also met with FDA officials and the Chairman traveled to England with majority and minority staff to interview British and Chiron officials.

The documents show that FDA failed to provide effective oversight. Expert scientists at FDA knew about serious problems at the Liverpool facility in June 2003, but there was not sufficient leadership at the agency to ensure that they were fixed.

My staff prepared a background memorandum for this hearing that describes the documents and their significance in detail. I ask that this memorandum — and the redacted versions of documents cited in the memorandum — be made part of this hearing record.

The Chiron plant in Liverpool was not an ordinary FDA-regulated facility. It's a facility with a history of contamination problems that makes half of the U.S. supply of flu vaccine. The plant should have received the highest priority from FDA.

Yet the agency ignored glaring problems at the facility and missed repeated opportunities to correct them.

I have been in Congress for 30 years. Throughout this period, oversight of FDA has been one of my highest priorities. I drafted many of the major laws that the agency implements, including the Orphan Drug Act, the Hatch-Waxman Act, the Nutrition Labeling and Education Act, the Safe Medical Devices Act, the user-fee law that accelerated drug approvals, and the Food Quality Protection Act.

That's why I have become so concerned about how the agency has performed in recent years.

What we are witnessing is the dismantling of FDA's enforcement and oversight capabilities. In area after area, the agency is failing to enforce the public health laws that Congress enacted. Enforcement actions for misleading drug advertisements have dropped 70% since 2001. Enforcement actions at vaccine plants and other manufacturers of biologic drugs have dropped over 80%. Key food labeling laws are being ignored.

And there is no better example of what's wrong at FDA than its failures at the Chiron vaccine facility.

The story told in the FDA documents begins in June 2003, when a team of FDA inspectors visited the Liverpool facility and found 20 serious problems at the plant, including bacterial contamination and poor sanitary practices. The FDA experts who conducted the inspection recommended that the agency take official enforcement action against the company.

Yet this recommendation was rejected. FDA "downgraded" its response and asked the company to make only voluntary reforms.

FDA's justification for failing to cite the facility is that the agency thought conditions were improving. But conditions weren't improving; they were deteriorating. Over the next 16 months, as production at the facility increased, the problems found in June 2003 mushroomed.

Yet during this entire period, FDA never once revisited the plant to see if Chiron was correcting its problems and making safe vaccines.

Incredibly, FDA remained passive even after August 25, 2004, when Chiron disclosed that millions of doses of vaccine were contaminated by a potentially lethal form of bacteria.

A responsible regulator would have inspected the plant, demanded to review its production records, and convened high-level meetings of the agency's top experts. And that's exactly what the British regulators did. A senior British health official summed up their philosophy as "Seeing is believing."

By contrast, FDA conducted oversight by conference call, trusting a stream of false assurances by Chiron that the plant had no serious problems. FDA conducted no inspection; it reviewed no plant records; and it was caught completely by surprise when British regulators shut down the plant on October 5.

FDA's laxity has had a heavy cost. If FDA had ensured that the problems identified in June 2003 were fixed, this year's flu crisis might never have happened. And if FDA had responded aggressively to the contamination problems in August, our public health system would have had critical extra weeks to prepare for the shortage and to avoid the chaos that ensued in October.

It is essential for FDA to learn from its mistakes. But so far, the Administration has been unwilling even to admit them. In recent weeks, the President, the HHS Secretary, and the Acting FDA Commissioner have all reassured the public that FDA did everything right. The Acting Commissioner has even indicated he would do it all over again the same way.

After the flu crisis broke, Dr. Crawford told the public that the June 2003 inspection had "no relevancy" to the problems found in 2004. He said that FDA monitored the actions of Chiron and ensured that the violations found in 2003 were corrected. And he said that the U.S. and British regulators acted "in synchrony."

None of these statements were true. In this Administration, inconvenient facts are simply ignored. This is a dangerous way to govern — and it is particularly hazardous for the public health.

I expect that the Chairman may disagree with me today about the interpretation of some of the FDA documents. That's his right. But even as we disagree over specifics, I want to commend the Chairman for his approach to this hearing. He has asked for the right documents and he has worked with me to ensure that we can release redacted copies so that members and

the public can judge their significance for themselves. That's exactly the right way to approach this important hearing.

I look forward to the testimony of the witnesses.